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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,561	03/19/2002	Jerry M Collins	31978-178825	6698
26694	7590	03/31/2005		
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER JONES, DAMERON	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 03/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,561

Applicant(s)

COLLINS ET AL

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 41-56 is/are pending in the application.
- 4a) Of the above claim(s) 50-56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 13-31 and 41-49 is/are allowed.
- 6) ☒ Claim(s) 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 12/6/04 wherein claim 13 was amended and claims 50-56 were added; and claims 32-40 are canceled.

Note: Claims 1-31 and 41-56 are pending.

RESPONSE TO APPLICANTS ARGUMENTS

2. The Applicant's arguments filed 12/6/04 to the rejection of claims 8-19 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejection

- I. The rejection over claims 13-19 is WITHDRAWN for reasons of record.
- II. The rejection of claims 8-12 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 8/6/04 and those set forth below.

Applicant asserts that the terms 'modulator of cellular accumulation mechanisms' and 'modulator' are explained on page 15, lines 12-20 and page 15, line 28 through page 17, line 24.

Applicant's arguments are not persuasive. Applicant refers to the above cited pages for support of the terminology and definition of what is being claimed. First, page 15, lines 12-20, disclose the duty of a modulator, but the paragraph does not set forth a group, class, compounds, or clear definition of what species are encompassed by the

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phases that are compatible with the instant invention. Page 15, line 28 through page 17, line 24, disclose that cellular accumulation mechanisms include various transport systems within a cell that affect the accumulation of anti-tumor drugs and other compounds. Re-reading pages 15-17 indicate that various preclinical and clinical studies are underway to find agents that are applicable in the instant invention. In addition, the pages are directed to limited compounds that disclose definitive data. Thus, the invention has not been described with such clarity that the reader is assured that the inventor actually has possession and knowledge of the modulators unique to the instant invention. What the claim terminology sets forth is a plan to accomplish an intended result.

ELECTION BY ORIGINAL PRESENTATION

3. Newly submitted claims 50-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claims are directed to subject matter wherein additional limitation not previously examined have been included.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 50-56 are withdrawn** from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

ALLOWABLE CLAIMS

4. Claims 1-7, 13-31, and 41-49 are allowable over the prior art of record for reasons of record in the office action mailed 2/24/04.

COMMENTS/NOTES

5. The starred (*) document appearing on the PTO-892 and not included with this office action was submitted with Applicant's response filed 12/6/04.

6. It should be noted that no prior art has been cited against Applicant's claims 8-12; however, Applicant **MUST** address and overcome the 112 rejections above.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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March 28, 2005